

Xenobiotic Detection Systems, Inc.

"Dioxin Bioassays"



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Dr. William Stokes
Director of NICEATM
National Toxicology Program
P.O. Box 12233
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Research Triangle Park, NC 27709

RE: Written Public Comments on SACATM and "Five Year Plan for ICCVAM/NICEATM"

Dear Dr. Stokes:

I attended the SACATM meeting that was recently held at NIEHS and made brief public comments at the meeting. Xenobiotic Detection Systems (XDS) is one of the developers of alternative technologies to refine, reduce, and replace animal use in testing chemicals to protect Public Health. XDS is therefore a stakeholder and is submitting written comments on the "Five Year Plan for ICCVAM/NICEATM". I have written some bulleted points after discussion with Dr. John Gordon, Director Research and Andrew Chu, Laboratory Director and the rest of our staff. Please feel free to call me or to schedule a meeting to discuss these items more fully. XDS believes that the program you are heading is very important and should be supported to protect Public Health and reduce the use of animals in the mission of protecting the public.

- **Priority Setting:** I agree with the comments made by Dr. Thomas Hartung, Director of ECVAM, on this item at the meeting. Priority setting is necessary to direct efforts because there is limited funding for your mission. The 9 priority areas that you have identified seem appropriate but should not limit efforts to only these areas. Selecting specific Public Health issues to direct funding efforts is a difficult task and priority setting may be handled by identifying areas in which alternative technologies already exist. This would focus efforts to bring existing technologies into use to protect Public Health. Developing alternative methods for multiple adverse health endpoints rather than multiple assays for only one problem is another form of priority setting and will have a greater effect on reducing, refining and replacing animals.
- **Accelerate the Process:** I worked in the pharmaceutical industry and one of their greatest efforts is to accelerate the process of bringing a drug to market in the complex regulatory environment of the FDA to protect human health. Acceleration of the process of bringing an alternative method to validation and regulatory

acceptance also needs to be expedited. Dr. Hartung provided some comments on this issue during the meeting. His agency supports validation without a complete validation process if the data is overwhelming that an alternative assay can refine, reduce, and replace the use of animals in testing of chemicals for potential adverse health effects. Implementing the use of abbreviated validation for use by ICCVAM/NICEATM would also accelerate the process to protect Public Health and provide new technologies to refine, reduce, and replace animal use.

- **Limited Funding:** There are increasing strains on government funding for research and efforts should be expended to compete for the availability of funding to support your important mission. Sara Amundson, Executive Director of The Humane Society, made some public comments on this issue during the meeting. The stakeholders should be engaged to expend efforts in increasing funding for research and for ICCVAM/NICEATM to support Public Health efforts and the mission of refining, reducing, and replacing the use of animals in research.
- **Granting Program:** Dr. Barile, St. Johns University and a member of the SACATM, made this suggestion. A granting program to support the mission may be a great way to develop alternative technologies for the benefit of Public Health. New technology for testing chemicals needs to be supported. There are granting programs already in existence to support research and development of alternative technologies and these could be focused and expanded. However, these granting programs do not support validation efforts. NICEATM is unique in that it supports validation efforts that are necessary for regulatory acceptance of alternative methods.
- **SACATM use in peer review process:** There are multiple points for peer review in research, development and validation of alternative technologies for regulatory acceptance. SACATM is a sitting panel of peer review experts having the appropriate knowledge in this scientific field and could be used for accelerating the process of peer review for ICCVAM/NICEATM.

I hope that you, NICEATM, ICCVAM, NTP, and NIEHS will review my suggestions for the “Five-year plan for ICCVAM/NICEATM”. I believe your mission is valuable to Public Health and hope that XDS may continue to contribute to this mission.

Best regards,

George C. Clark, Dr.P.H.
President

Cc: Dr. David Schwartz, Dr. Leonard Schechtman, Dr. Thayer, Dr. Thomas Hartung, and Dr. Kojima